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ANTHROPOLOGY, DOTS AND UNDERSTANDING TUBERCULOSIS CONTROL IN NEPAL

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Summary. This paper argues for the inclusion of ethnography as a research methodology for understanding the effects of public health policy. To do this, the implementation of DOTS (Directly Observed Therapy, Short-course) – the World Health Organization (WHO) prescribed policy for the control of the infectious disease tuberculosis – is explored in the context of Nepal. A brief history of DOTS and its implementation in Nepal is outlined, and the way it has been represented by those within the Nepal Tuberculosis Programme (NTP) is described. This is followed by an outline of the research done in relation to this, and the ethnographic methods used. These ethnographic data are then interpreted and analysed in relation to two specific areas of concern. Firstly, the effects around the epidemiological uses of ‘cases’ is explored; it is argued that a tightening of the definitional categories so necessary for the programme to be stabilized for comparative purposes has profound material effects in marginalizing some from treatment. Secondly, the paper examines some of the implications and effects relating to the way that the ‘directly observed’ component was implemented. The discussion explores how current debate on DOTS has been played out in some medical journals. It argues for the importance of ethnography as a method for understanding certain questions that cannot be answered by particular, and increasingly dominant, research ideologies informed by randomized controlled trials. This raises important issues about the nature of ‘evidence’ in debates on the relationship of research to policy.

DOTS in Nepal

Directly Observed Therapy, Short-course (DOTS) policy includes five essential elements, namely: political commitment to increasing resources and including tuberculosis (TB) control as an activity integral to national health systems; good, widely available sputum microscopy services so that the disease can be correctly identified; standardized short-course chemotherapy, including the direct observation of treatment; uninterrupted supply of drugs; and, finally, recording and reporting

systems (WHO, 2002). In Nepal, following a joint HMG/WHO review of the Nepal National Tuberculosis Programme (NTP) in 1994, DOTS was adopted as national policy in 1995, with implementation starting in early 1996. Positive results in four districts led to expansion covering about 20% of the population by mid-1998. The whole programme remains oriented towards the 'internationally' (that is WHO) defined targets of finding 70%, and curing 85%, of patients with infective tuberculosis. Simultaneously, in 1993 the Tuberculosis Control Network was started, in which a number of NGOs working in the realm of TB control linked up with the NTP to address issues of common concern. These included standardizing treatment protocols, manuals and the organizational recording and reporting formats so that programmatic comparisons and the training of staff would be consistent and easier. By 1999, when the fieldwork upon which this paper is based was ongoing, the programme had been expanded to cover over 50% of the country. By 2001 the head of the National programme was able to represent the programme in the following way on a website set up to deal with global tuberculosis issues, to showcase Nepal as an exemplar of what is possible to achieve with DOTS:

DOTS was introduced in 1996 after a joint His Majesty's Government of Nepal (HMG/N)/WHO review of the National Tuberculosis Programme (NTP) revealed that only 30% of TB cases were registered under the NTP and of these, only 40% were treatment successes. The cure rate in the first cohort of DOTS patients was above 89%. By July 2000, the programme had been expanded to 183 treatment centres in 69 districts and covers 78% of population. The treatment success rate in the DOTS centres remains at approximately 89%, with the national treatment success rate now reaching almost 85%. Nationally, this year over 28,000 TB patients have been registered and are being treated under the NTP. Out of these, over 75% are being treated under DOTS. (Bam, 2001)

This needs to be placed within the context of the overall delivery of primary health care services. Economically, by the year 1999 total spending on health care in Nepal's public sector remained grossly under-funded at US\$1.8 *per capita* per year, rising to US\$3.1 when donor funding was taken into account. It remained at about one-quarter of the level needed to provide even a basic essential package of health services in a developing country, as suggested by the World Bank (World Bank, 1999). Within this, the annual funding for the National Tuberculosis Programme from the government rose from 25 million rupees (1 US\$=69 NPR) in 1995/96 to 63.5 million rupees in 1998/99 (NTP & HMG/N, 1999). Assistance from a number of other sources added another US\$2.5 million. The Department for International Development (DfID-UK), the International Union Against Tuberculosis and Lung Disease (IUATLD), the Japanese International Co-operation Agency (JICA), the Japanese Government, the Norwegian Lung and Heart Foundation, NORAD, the Nuffield Institute for Health, the Research Institute of Tuberculosis, Japan, and the WHO assisted at the national level financially, technically and with research. Programme implementation was assisted at a regional and district level by a number of international and national non-governmental organizations (INGOs and NGOs). Structurally, the National Tuberculosis Centre, the building, lies some distance from the Department of Health Services. Although the National Tuberculosis Programme is said to be 'integrated' into the national health system, the Director of the National Tuberculosis Centre (NTC) also manages the NTP, and the agenda remained very much a vertical disease programme. The NTC, and their staff, provided the technical

support (planning, monitoring, training, supervision, logistics, laboratory services, health information education and research) to the TB control activities, at national, regional and district levels (NTP & HMG/N, 1999).

The expansion of the programme started in the districts that had been able to adhere to the strict protocols for the introduction of short-course chemotherapy (SCC). Short-course chemotherapy is called 'short-course' as it replaced the standard drug regimes of the past with an entirely oral one that substituted the injectable streptomycin with the drug rifampicin, and the regime needed only be given for six to eight months rather than a year. In Nepal, DOTS was adopted as national policy following the gift of free rifampicin from the Japanese Government, as part of their aid package, to the National Tuberculosis Programme and amid fears that this would produce an epidemic of multi-drug resistant TB (MDR-TB) once the markets were flooded with this drug (Fryatt, 1995). National DOTS policy rapidly expanded to include most districts of Nepal. As a part of the above collaborative research efforts in Palpa District – one of the 75 administrative districts into which Nepal is divided, and where I did most of my fieldwork – had been randomized as a part of a trial comparing the use of female community health volunteers (FCHVs) with family DOTS. This was one of the areas that the NTP, heavily influenced by the WHO, had identified as important to research: namely ways to implement the DOT component of the DOTS programme. Differing treatments in Palpa up to this time were available from a range of private doctors and pharmacies, including a mission hospital. The DOTS clinic was set up in the public hospital and the free treatment through the revitalized National Tuberculosis Programme was being made available from the state-run primary health centres and health posts. Prior to its introduction, a whole series of training sessions were conducted at the district centre, and from health posts, to raise awareness of the programme. These were facilitated by staff from the NTP. All health workers were targeted, as well as the FCHVs. Simultaneously, new recording and reporting strictures were introduced, along with new protocols for the treatment of patients. Regular meetings were instituted and held at health posts and in the district centres every four months to facilitate the reporting of outcomes to the centre, and the reordering of drugs based on consumption patterns.

Methods

My research in anthropology sought to understand how a number of public health programmes, of which DOTS was one, were taken up and translated in practice within the health services in Nepal. In order to do this research I did fieldwork in the form of participant observation from September 1998 to March 2000. This, the process of doing ethnography, is simply based on the premise that one of the best ways to understand a situation is to spend extended periods of time interacting with those involved in that situation (Monaghan & Just, 2000). This research involved spending long periods of time with staff in hospitals, health posts and TB clinics and working with the TB programme supervisors as they implemented the new policy and protocols; following up in the long term those diagnosed with the disease and attempting to understand the meaning they attributed to it within the contexts of their lives; understanding how both the ill, and those delivering biomedical services,

negotiated the diagnostic possibilities in an area where being ill can be dealt with by a richly diverse range of healers; and trying to understand how the rapidly increasing private pharmacies and national bureaucratic health services were integrated into this mosaic locally.

I started with a series of broadly stated and open-ended questions related to the above. Over time and during the process of observing, participating in, and questioning around what was happening I was able to acquire an understanding of these activities relating to health. As trust developed between myself and my subjects of research, and by allowing conversations to wander to the interests of the staff and patients, I was granted access into areas of their work and lives that no amount of questionnaires could generate. I have also been trained as a medical doctor and had worked in TB clinics so I was able to discuss the concerns of the staff in relation to the work. Much of the data, then, were dependent upon my own subject position: that is how I was perceived by those I was researching with and the influence this had on how they interacted with me.

Descriptive ethnography and interpretation

Case definitions and programmatic representation

The findings were multifaceted generating both support for the current policy and significant challenges to aspects of it. At a national level and translated down to the district, the raised awareness and political will to deal with TB were increased substantially, and this heightened public awareness of tuberculosis as a health problem. Health staff became both more aware of tuberculosis as a disease and of the need to treat it for sustained periods and the dangers of interrupted treatment. By standardizing recording and reporting formats, it became possible to follow up and report on outcomes, something that was limited prior to the start of the DOTS programme itself. Short-course chemotherapy was introduced and drug supplies improved. The standardizing of treatment protocols and the diagnostic categories (i.e. what makes a 'new smear positive case' etc.) and the training involved for staff disseminating this, resulted in increased collaboration between some institutions. Cross-referrals between hospitals and clinics became possible, without the complex task of having to change drug regimes. From this broad perspective, then, as with those who suggest that we should limit our criticisms of DOTS to the pre-DOTS 'chaos' that I discuss later, there were significant, and from the perspective of the control of tuberculosis, positive changes.

However, such a picture would be misleading if other issues were not also touched upon. The standardizing of the definition of categories of patients, so necessary for programmatic comparative purposes, resulted in the emergence of a whole new set of difficulties. A 'new' smear positive patient, here as everywhere, was redefined as anyone presenting to the health centre for the first time, *and* having received less than one month's treatment from elsewhere. Within epidemiology, it is inevitably the case that if one is to compare programmatic performance and output, a tight definition of a 'case' of tuberculosis is necessary. But one of the unintended consequences of this drive to compare, at least in the district of Palpa, was that about 20% (as the staff

and I calculated in the DOTS clinic) of patients presenting to the clinic who had received more than a month's treatment from the private sector were not being allowed into the National Tuberculosis Programme. As more than 200 were registered into the programme this is a significant number. Paramedical staff had been trained to implement the new protocols, but they had not been taught (the admittedly complex) task of deciding what to do for these pharmaceutically complicated patients.

During discussions with staff about the difficulties they faced in their work, they frequently referred to the training and seminars that they had been sent to, organized by the NTC in Kathmandu. Some of the explanations and difficulties encountered in categorizing patients along the new NTP guidelines were as follows. How was it possible to know that these patients presenting to the NTP had tuberculosis in the first place – they may not have had tuberculosis at all and been placed inappropriately on treatment? Even if they had, they may or may not have been 'smear positive' (the diagnosis protocol states that this is dependent upon visualizing the causative organism in the sputum under a microscope). If they were 'smear positive', and they had taken their drugs intermittently, then they could already be 'resistant' to first-line treatment, the drugs recommended for those in this category. However, they were not strictly 're-treatment' cases either – another centrally defined category. For this there needed to be proven defaulting from treatment, or it was necessary to know that they had completed treatment and were labelled as 'relapsed'. In discussion with the clinic staff, given that their autonomy to make individual decisions had been restricted and curtailed by the research and diagnostic protocols, they struggled continually to place patients into these categories.

Now policy allowed that the qualified doctor in the public hospitals made decisions around these pharmacologically complex, and potentially drug-resistant patients. In this district (and indeed in many others, particularly the remoter ones), however, these doctors were frequently absent, often for months at a time, and were not replaced. It was ironic in the extreme, that for a period of three months during my research one such doctor in Palpa was at a training course in Thailand on understanding infectious disease surveillance! But the consequence was that unsupported, all the junior staff could do was to deny these medically complex patients further management within the system, and they were referred back to the hugely expanding private sector to further receive their potentially erratic treatment.

This ethnographic information, gathered after a long period with staff in the district, raises many important questions overlooked by public health specialists and researchers in Nepal. Firstly, is it possible that the very programme designed to prevent the rise of MDR-TB is unwittingly complicit in its generation and spread? While individual compliance is continuously reiterated as the major cause of this – and the justification for DOT – ethnographic data suggest that other factors may be as big a problem. Secondly, as pharmacologically complex patients are not even allowed entry into the NTP figures, it is likely that at the very least the official figures significantly overestimate the success of the programme. Those most likely to be cured are the ones entered into the NTP, while those least likely to be cured – those whose treatment has been interrupted – are denied access. Not included in current figures are these cohorts who do not get in. It is probable, therefore, that the most likely to develop MDR-TB are not even a part of the figures. This becomes a vitally important

question of interpretive framing, and how national data are presented, as much as about the 'facts' themselves. It is also clear that the desire for accurate cohort information and the tightening of definitional and diagnostic categories may also be a part of the problem itself as the social processes that generate the facts, through processes of exclusion, simultaneously distort the nature of the reality it seeks to represent.

The problems with Direct Observation of Therapy

Palpa District, as a part of the trial comparing direct observation possibilities, had been randomized so that local female community health volunteers (FCHVs) were used for this purpose. For many of the ill, those fortunate enough to live close to health centres and these volunteer staff, this was frequently helpful. Mobilizing these workers and training them helped raise awareness of tuberculosis and that it was a treatable, infectious disease. Quite quickly, however, it became possible to recognize that this form of support was not always in the patients' best interest. Patients were informed upon being registered into the programme that they had to return to the clinic with the volunteer to receive treatment and instructions. These volunteers, rather than the patients themselves, were then entrusted with dispensing the medicines, and directly observing that they were swallowed. One man I followed up who had not returned to a health post with the FCHV as instructed had been too busy with the rice harvest. He had died without even receiving treatment. Another man I interviewed who had been severely debilitated as a consequence of his disease pointed out how difficult it was to walk anywhere in these steep mountainous regions if you had tuberculosis. Several of the FCHVs I visited on one trip, themselves local women and equally busy, were just giving the drugs to patients often for a month at a time. Moreover, at one training session I attended, they complained that they were expected to do more and more work (pulse polio, Vitamin A distribution, and other health monitoring activities for example) as they had become the focus of considerable efforts to improve health service provision.

But there were a number of other reasons why the direct observation of the treatment was frequently difficult. Many with the disease, particularly younger women, wished to avoid the stigma associated with it. For many this was a disease linked to notions of impurity, and locally widely associated with dirt and poor habits like drinking and smoking. The shame associated with having the disease, and the understandable desire to remain anonymous while receiving treatment, became harder with this system. The increased surveillance made issues of patient confidentiality all but impossible. The disease and ideas around its causes were also frequently interpreted into the dominant caste ideology in the area. One consequence was a general reluctance for many of the higher caste supervisors – and nearly all the supervisors were higher caste – to offer water to lower caste patients with the disease, to help in swallowing their tablets. This relates to religiously sanctioned notions of purity and impurity, defined by the dominant and mainly Hindu religious ideology in the area. A consequence, as was pointed out by several health workers I had conversations with, was that this support added to the reasons for default for some lower caste patients.

Also in a health structure that reflects some of the broader social hierarchies (cf. Nichter & Nichter, 1996, for an Indian comparison) more senior members of the NTP and supervisors frequently did not listen to the valid suggestions of the staff, such as being more flexible with direct observation. Supervisors just demanded – frequently in long monologic speeches to the staff – that this district policy be continued. When the staff at one district level meeting suggested that just using FCHVs was not practical, the response from one regional supervisor was that they just had to carry on. Using FCHVs was national policy the group was informed. There was a tendency, also, for senior staff to suggest that those below them in the hierarchy ‘did not understand’ the necessity for daily observation and so required further training and further technical instruction into its necessity. As a consequence of this, as I was told by one health worker, what they needed to do to keep their jobs and not be transferred was to tell their bosses what it was that they wanted to hear. A number of staff understood that DOT was not in the interests of the patients and ignored it, and attempted innovative ways of adapting their procedures, giving weekly drugs or more to the patients as they arrived, for example. But other health workers hid behind the DOTS ‘rules’ inflexibly. One DOTS worker I sat with would not give a week’s worth of drugs for patients to travel to his relative’s home at an important festival time. It was for reasons like this that another health worker dubbed the DOTS programme the ‘defaulter creation system’.

There are, then, a variety of social relations, some broadly speaking cultural and others linked to hierarchy in the health system, into which the DOTS programme falls. Both health workers’ and patients’ reactions to the implementation of this programme were varied. But my own research experience suggests that given the right conditions and supervisory support, most of the staff would work out appropriate strategies for dealing with the vexed question of adherence to treatment. This requires a different relationship, however, with the staff, and an understanding of how the rigid requirements of a research agenda linked to the health service can feed counterproductively (from the perspective of patient support) into already existing social hierarchies.

Discussion

In 2004, the WHO published its 8th annual report on global tuberculosis control (WHO, 2004). Two hundred and one countries – including Nepal – reported on their strategies for TB control, as well as on their TB case notification and treatment outcomes. This in itself is a remarkable achievement, as in 1990 assessment in most developing countries was virtually non-existent, because of the poor development of information systems, both at country and global levels (Raviglione, 2003). This shift was facilitated by the development of the DOTS strategy, spearheaded by the WHO, and which has been aggressively promoted via strategies that marketed the approach to policy-makers and programme implementers. As the 2004 global report introduces it, DOTS is ‘a management strategy for public health systems’, not guidelines for individual clinicians (WHO, 2004, p. 11). One consequence of its simplification and marketing has been a rift and considerable disagreement between those who advocate it, and a number of researchers and academics who felt that it was too simplistic

(Ogden *et al.*, 2003). Within this, and in the published literature, most of the criticisms of the DOTS strategy have fallen onto the 'direct observation' component. The uncritical insistence that DOT is a mandatory component of this strategy has led some commentators to suggest this places a primacy in 'faith' over that of 'science' (Garner & Volmink, 2003), and that the structure and functioning of DOTS programmes have not been substantiated in rigorous, empirically based trials (Mudur, 2004). The defence of the DOTS strategy by those who advocate it, has been to underplay the DOT component of it and highlight how it acts to mobilize resources, secure regular supplies of drugs, increase political commitment and improve monitoring of outcomes (see, for example, Gunneberg, 2004) – or that what is important to consider is the comparison of 'the ramshackle chaos of a pre-DOT programme with a new DOT programme in the same setting' (Davies, 2003).

Most of the arguments for and against DOT have been developed from evidence of a few key trials that have compared direct observation of treatment with that of self-treatment (Zwarenstein *et al.*, 1998, 2000; Kamolratanakul *et al.*, 1999; Walley *et al.*, 2001). It is on the basis of the evidence in these internationally published papers – based on research in South Africa, Pakistan and Thailand – that Garner and Volmink set up their 2003 editorial questioning DOT in the *British Medical Journal* (Garner & Volmink, 2003). This highlights an important aspect of the debate as played out in medical journals: that what is most frequently valorized is a particular logic of scientific enquiry – the randomized controlled trial – as the authority and grounds for comment. This is despite an increase in the number of calls for cross-disciplinary research and good examples of this (see, for example, the contributions to Porter & Grange, 1999), and that there is already much research focusing on socio-cultural and political-economic issues in social science and anthropology journals that have focused on tuberculosis (Ho, 2004).

While the WHO have recently acknowledged that randomized controlled trials are limited in their use for evaluating DOTS (something they argue strategically and most strongly when these trials question the value of DOT), they still warn that it is essential that ethical consideration needs 'to be given to any study design that differs from globally recommended policy, and in most countries, national policy as well' (Maher *et al.*, 2003). While I think that it is disingenuous to defer to the higher authority of an undefined 'ethics' in defence of DOT, it is to be commended that the WHO recognize the need for a greater methodological diversity in understanding the impact and effects of the DOTS programme in a variety of settings (Ibid.). More concretely, also in response to this editorial, Macq suggests that it is important to develop methodologies that move away from statistical and 'inference-based' reflection, to ones that promote context-sensitive and qualitative knowledge generation (Macq, 2004).

Here questions surface around the complex relationship between more positivist scientific disciplines and those that are reflexively more interpretive. The relevance of local, nuanced data that are generated through a research method that is 'inter-subjective' rather than claiming to be objective is at stake here. This raises questions, too, around the generalizability of what can be inferred from such research data. How do we anthropologists defend, then, what we deem our disciplinary strength: understanding the local, the particular and all the nuance of human interaction within

broad historical, social and political fields? What is the relevance to medical and public health discourse, whose frames for *verifiability* and *generalizability*, are still largely unchallengable? The difficulties of engaging work that is inter-subjective, frequently literary in writing style and very local with work that is positivistic, based in 'enlightenment' principles and for broad population-based policy agendas should not be underestimated (Kleinman, 1995). I have presented aspects of my work to those involved in the programme in Nepal – from the WHO advisor to others – but the response was a form of silencing, by asking in what sense my findings in Nepal were *generalizable* to the rest of Nepal. It was pointed out that policy could not be dependent on data – deemed anyway to be in the main little more than my own opinion (i.e. too subjective and interpretive) – from just one small area. Given that the policy itself was also not based on much evidence this argument seems disingenuous, but more importantly it raises issues on the relations of policy with research, and of the relationship between value and science. Once a particular policy gains momentum, political expediency becomes the primary driving force, and in its wake the burden of proof required to challenge predefined policy rises.

For audiences informed by this scientific ideology, how might we clear the space for a more anthropological agenda? This must be more than adding a few methods to do 'the cultural piece' (Farmer, 1999); that is, the type of research that seeks to understand cultural practices and beliefs that act as 'barriers' to control or as reasons for default from treatment, for example. While there may be a place for this type of research, this is just one strain of medical anthropology, called by Byron Good 'the persistence of the empiricist tradition' (Good, 1994). Anthropology has much more than this to offer. At its best anthropology is able to 'reconfigure the boundaries of the problem', offering (new) conceptual frameworks, substantive knowledge and methodological insights (Lambert & McKevitt, 2002). The work of Paul Farmer is but one example, as he brings in a broader political and economic frame, issues of 'structural violence' and how this impinges on the more vulnerable and marginalized in both developing tuberculosis, and how their lack of agency limits their consequent access to treatment (see, for example, Farmer, 1999). The findings presented in this paper highlight the mistaken assumptions embedded in public policy: that research clearly needs to include within its frame an exploration of the unintended effects of policy and research itself; the need for greater critical awareness of the conceptual framing devices, and the biases of programmatic representations. In the light of this work I would call for much greater flexibility in implementation strategies of TB control.

While there is a range of important research currently being conducted under the auspices of, and in partnership with, the NTP in Nepal, this could be considerably strengthened by considering the value of, and need for, more qualitative research. None of it focuses on the more historical, political and economic issues. Conceptually, the narrowing of fields of vision of current research from the NTP, so obviously defined by a dominant medical ideology, is unlikely to pose these more difficult questions; this at present comes from the perspective of the stabilization of the system (see I. Harper, in press) rather than the perspectives of the patients. To understand why default occurs, as one example, requires this broader conceptualization and cannot be answered by randomized controlled trials. Re-conceptualizing the issues

will also lead to new research agendas. Research should also pose questions about the relationship between TB and poverty in the Nepal context, and will have to address questions around the 'structural violence' of civil war, internal migration, emerging famine in the far west of the country and the relations of this to both developing TB, and access to TB treatment. None of this, however, can be done under frames of reference that need controlled populations for the comparison of treatment outcomes. Anthropological research should be a part of the greater interpretive imagination – that which comes from an appreciation of inter-disciplinarity. As the particular contexts of the work and lives of those who have TB, and those who try to deal with it, become exposed to ethnographic research so too will new framings and not always easy questions arise. Rarely do anthropological data or interpretation fit the dominant frames of reference. They can be ignored, or, a better understanding of the value of such research can be developed.

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